

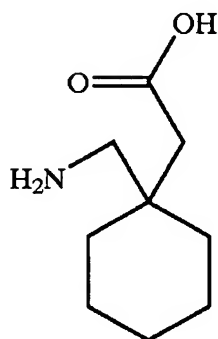
IN THE CLAIMS:

The text of all pending claims, (including withdrawn claims) is set forth below. Cancelled and not entered claims are indicated with claim number and status only. The claims as listed below show added text with underlining and deleted text with ~~strike through~~. The status of each claim is indicated with one of (original), (currently amended), (cancelled), (withdrawn), (new), (previously presented), or (not entered).

Please amend the claims as noted below.

Listing of the Claims

1. (Currently amended) ~~An improved~~A process for the preparation of ~~gabapentin~~
Gabapentin of the formula 1



gabapentin

which comprises:

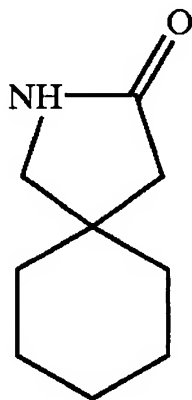
- (i) preparing an aqueous solution of Gabapentin hydrochloride in water in ~~the a~~ ratio of one part by weight of the ~~former Gabapentin hydrochloride~~ to 0.5 to 3 parts by weight of the ~~later water~~;
- (ii) preparing an aqueous solution of an alkali metal base in a concentration in the range of 40-50% w/w;
- (iii) adding 0.08 to 0.3 parts by weight of the solution obtained in step (ii) to 1.5 to 4 parts by weight of the solution obtained in step (i) at

a temperature in the range of 0 to 20 degree C to form a resulting solution;

- (iv) heating the resulting solution gradually to a temperature in the range of 50-90 degree C;
- (v) gradually cooling the resulting solution to a temperature in the range of 0 to 15 degree C to obtain a precipitate;
- (vi) aging the precipitate for a period of time in the range of 0.5 hrs to 8 hrs at a temperature in the range of 0 to 15 degree C;
- (vii) ~~Separating~~ separating the precipitate from ~~the~~ its mother liquor by conventional methods; and
- (viii) recrystallising the precipitate from a mixture of isopropyl alcohol (IPA), methanol & water to get Gabapentin of over 99.5% purity and ~~a~~ another mother liquor.

2. (Currently amended) ~~An~~ The ~~improved~~ process as claimed in claim 1, wherein the amount of the gabapentin hydrochloride and the water used in step (i) is in the ~~range~~ ratio of 0.5 to 2.5 parts of water to 1 part of the Gabapentin hydrochloride ~~and or in the ratio of more preferably 1.5 to 2.5 parts of the water to 1 part of the~~ Gabapentin hydrochloride.
3. (Currently amended) ~~An~~ The ~~improved~~ process as claimed in claim 1, wherein the alkali metal base used in step (ii) ~~may preferably be~~ is sodium hydroxide, or potassium hydroxide, ~~more preferably sodium hydroxide~~.
4. (Currently amended) ~~An~~ The ~~improved~~ process as claimed in claim 1, wherein the solution of the alkali metal base used is in a concentration in the range of 40-50% w/w in water ~~more preferably~~ or in the concentration in the range of 45-50% w/w in water.

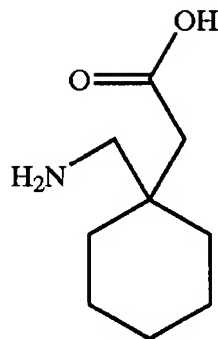
5. (Currently amended) ~~An~~The improved process as claimed in claim 1, wherein the temperature employed in step (iii) is ~~preferably 10 to -20 deg C, or, and more preferably 10- to 15 deg C.~~
6. (Currently amended) ~~An~~The improved process as claimed in claim 1, wherein the temperature employed in step (iv) used is in the range of ~~preferably be 50 to- 75 deg C; or in the range of and more preferably 60- to 70 deg C.~~
7. (Currently amended) ~~An improved~~The process as claimed in claim 1, wherein the temperature employed in step (v) is in the range of ~~preferably 5- to 15 degree C; deg and more preferably or in the range of 5 to- 10 deg degree C.~~
8. (Currently amended) ~~An improved~~The process as claimed in claim 1, wherein the time employed for aging the precipitate in step (vi) is ~~preferably be between 0.5 to 3 hrs and more preferably~~or between 0.5 to 1 hr.
9. (Currently amended) ~~An improved~~The process as claimed in claim 1, wherein the separation of ~~gabapentin~~Gabapentin in step (vii) is effected by filtration, ~~more preferably or~~ centrifugation.
10. (Currently amended) A ~~novel~~ improved process for the preparation of Gabalactam of the formula 3 represented by:



which comprises:

- (i) preparing an aqueous solution of Gabapentin hydrochloride in water in a ratio of one part by weight of the Gabapentin hydrochloride to 0.5 to 3 parts by weight of the water;
- (ii) preparing an aqueous solution of an alkali metal base in a concentration in the range of 40-50% w/w;
- (iii) adding 0.08 to 0.3 parts by weight of the solution obtained in step (ii) to 1.5 to 4 parts by weight of the solution obtained in step (i) at a temperature in the range of 0 to 20 degree C to form a resulting solution;
- (iv) heating the resulting solution gradually to a temperature in the range of 50-90 degree C;
- (v) gradually cooling the resulting solution to a temperature in the range of 0 to 15 degree C to obtain a precipitate;
- (vi) aging the precipitate for a period of time in the range of 0.5 hrs to 8 hrs at a temperature in the range of 0 to 15 degree C;
- (vii) separating the precipitate from its mother liquor by conventional methods;
- (viii) recrystallising the precipitate from a mixture of isopropyl alcohol (IPA), methanol & water to get Gabapentin of over 99.5% purity and another mother liquor;
- (ix) treating the mother liquors obtained in from steps (vii) & (viii) of the above mentioned process with an aqueous sodium hydroxide in a concentration in the range of 5 to 20% at a temperature in the range of 80 to 100 degree C; and
- (x) recovering the gabalactam-Gabalactam by extraction with organic solvents.

11. (Currently amended) ~~A novel improved~~The process as claimed in claim 10, wherein in step (ix), the concentration of sodium hydroxide ~~used~~ ranges from 10- to 20%, ~~and the temperature used ranging ranges~~ from 80 to 85 ~~deg~~ degree C.
12. (Currently amended) ~~A novel improved~~The process as claimed in claim 10, wherein in step (x), the recovery of ~~gabalaetam~~ Gabalactam is effected by ~~extracting the reaction mixture~~ extraction with organic solvents ~~such as selected from the group consisting of~~ toluene, ethylene dichloride, methylene dichloride ~~or~~ and hexane, ~~preferably toluene~~.
13. (New) The process as claimed in claim 1, wherein the Gabapentin has a chloride content of 100 ppm or less.
14. (New) The process as claimed in claim 13, wherein the chloride content is 40 to 95 ppm.
15. (New) The process as claimed in claim 14, wherein the chloride content is 40 to 90 ppm.
16. (New) The process as claimed in claim 15, wherein the chloride content is 40 to 70 ppm.
17. (New) The process as claimed in claim 16, wherein the chloride content is 40 to 60 ppm.
18. (New) The process as claimed in claim 17, wherein the chloride content is 40 to 50 ppm.
19. (New) A process for the preparation of Gabapentin of the formula 1



gabapentin

which comprises:

- (i) providing an aqueous solution of Gabapentin hydrochloride having a ratio of parts by weight of Gabapentin hydrochloride to parts by weight of water from 0.5 to 3;
- (ii) at a temperature in the range from 0 to 20 degree C, adding 0.08 to 0.3 parts by weight of an aqueous alkali metal base solution at a concentration from 40 to 50% w/w to 1.5 to 4 parts by weight of the aqueous solution of the Gabapentin hydrochloride to form a resulting solution;
- (iii) heating the resulting solution gradually to a temperature from 50 to 90 degree C;
- (iv) then, cooling the resulting solution gradually to a temperature from 0 to 15 degree C to obtain a precipitate;
- (v) maintaining the precipitate in the solution at the temperature from 0 to 15 degree C for a time from 0.5 hrs to 8 hrs;
- (vi) separating the precipitate from its mother liquor; and
- (vii) recrystallising the precipitate from a solvent mixture containing isopropyl alcohol (IPA), methanol & water to obtain Gabapentin of at least 99.5% purity and having a chloride content of 100 ppm or less, and a lactam content of 0.05% or less,

wherein the process excludes an ion exchange conversion of Gabapentin hydrochloride.

20. (New) The process of claim 19, wherein the chloride content is from 40 to 50 ppm and the lactam content is from 0.01 to 0.045%.

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